Remarks

Claims 1-41 are pending the current application. Of these, claims 8, 13 and 18-41 are withdrawn from consideration. Claims 1-7, 9-12, and 14-17 are rejected.

Response to Restriction Requirement

The Examiner stated that Applicants' election without traverse of the invention of Group I, claims 1-17 is acknowledged. The Examiner also stated that claims 1-7, 9-12 and 14-17 read on the elected species. Additionally, the Examiner stated that claims 8, 13 and 18-41 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim. Additionally, the Examiner stated that election was made without traverse in a reply. Applicants stated in the reply that claim 18 is incorrectly written as a method claim and is meant to be a dependent claim of independent claim 1, i.e. a composition claim. However, the Examiner stated that claim 18 has not been amended and as a result, is withdrawn.

In response, claim 18 has been amended to recite, "[a] controlled-release composition as set forth in claim 1." As a result, it is believed that amended claim 18 reads on the elected species and should be considered along with claims 1-17 of the Group I election.

Claim Rejections - 35 U.S.C. §103

The Examiner stated that claims 1-7, 9-12 and 14-17 were rejected under 35 U.S.C. §103(a) as being unpatentable over Kosal, U.S. Patent No. 6,545,086, in view of Gray et al., U.S. Patent No. 6,040,307, and further in view of Ulrich, U.S. Patent No. 6,365,146.

More particularly, the Examiner stated that Kosal teaches an oil-in water emulsion composition comprised of a pressure sensitive adhesive, a surfactant, and a thickening agent for medical and personal care utility. (*See* Abstract; column 1, lines 16-24). Additionally, the

Examiner stated that Kosal teaches that the emulsion composition is used in medical applications, such as transdermal drug delivery and to maintain an active drug, such as a fungicide to the surface of the skin. (*See* Column 5, lines 14-30). The Examiner argued that while Kosal does not explicitly teach that the drug delivery to the skin in the form of sustained or controlled release, transdermal drug delivery is taught, it is well known in the art that transdermal drug delivery is used to provide a controlled release of a desired active agent to the skin of the subject or patient.

Moreover, the Examiner stated that without evidence to the contrary, the combination of the silicone component and surfactant comprising the oil phase would have been expected to be homogeneous. The Examiner also admits that Kosal does not explicitly teach that the active drug contained in the system is ketoconazole. However, the Examiner stated that Gray et al. teaches that ketoconazole is a fungicide useful for fungal infections of the skin, as well as systemic infections. (*See* Abstract; column 1, lines 15-21). Moreover, the Examiner stated that it is also taught that ketoconazole can be administered in a controlled release or controlled delivery manner, (*see* Column 6, lines 64-67), and that ketoconazole could be administered topically as a solid, semi-solid, solution, powder, or a viscous form. (*See* Column 7, lines 32-45).

The Examiner asserted that it would have been obvious for one of ordinary skill in the art, at the time of the invention, to prepare a composition comprised of the pressure sensitive adhesive, surfactant, thickener, and emulsion taught by Kosal and the active agent ketoconazole because Kosal teaches that the pressure sensitive adhesive comprised oil-in-water emulsion is effective for transdermal drug delivery, and for maintaining fungicidal active agents on the surface of the skin. Additionally, the Examiner argued that it would have been obvious to one of

ordinary skill in the art to have expected success in utilizing the composition taught by Kosal to deliver ketoconazole in a controlled release manner topically, for drug delivery.

The Examiner also stated that while Kosal does not explicitly teach that surfactants encapsulate the active agent, Ulrich teaches that surfactants are commonly used for drug delivery, as the micelles formed from the surfactant are able to solubilize hydrophobic drugs, within a hydrophilic outer shell. (*See* Column 1, lines 45-51). As a result, the Examiner stated that it would have been obvious that the surfactants taught by Kosal inherently encapsulate the active agent, ketoconazole.

Independent claim 1 recites a controlled-release composition for topical application to a substrate, said composition comprising an oil-in-water emulsion and an active agent incorporated into the oil-in-water emulsion. Independent claim 1 further recites that the oil-in-water emulsion is substantially free of lipophilic solvent and is formed by mechanical inversion of a water-in-oil emulsion comprising a silicone component, a surfactant, and water.

The Examiner failed to address the limitations of independent claim 1 wherein the oil-in-water emulsion is substantially free of lipophilic solvent and is formed by mechanical inversion of a water-in-oil emulsion. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). To expedite prosecution, the Kosal reference which the Examiner cited as disclosing an oil-in water emulsion composition comprising a pressure sensitive adhesive, a surfactant, and a thickening agent, is discussed in further detail below.

The specification discloses that, "[t]he O/W emulsion is formed by mechanical inversion of a water-in-oil (W/O) emulsion . . . and the O/W emulsion is substantially free of lipophilic solvent." (*See* Page 3, ¶ 0011). Additionally, the specification provides that, "[m]echanical

inversion of the W/O emulsion provides an effective process for emulsifying the silicone component without use of supplemental solvents to reduce the high viscosity of the silicone component." (*See* Page 4, ¶ 0011). More particularly, the specification discloses that, "[i]f the active agent is in powder form or crystalline form, as described below, then the terminology "substantially free of lipophilic solvent" denotes that the O/W emulsion is free of lipophilic solvent except for any lipophilic solvents present as a result of the silicone component. On the other hand, if the active agent is in liquid or viscous form, as described below, then the terminology "substantially free of lipophilic solvent" denotes that the O/W emulsion is free of lipophilic solvent except for any lipophilic solvents present as a result of the silicone component or as a result of any solvents in the active agent." (*See* Page 4, ¶ 0011).

Kosal discloses that his pressure sensitive adhesive emulsion is free of any non-silicon-containing volatile organic material. (*See* Column 1, lines 56-67). Kosal also discloses that, "[t]he invention also includes a process for the production of a pressure sensitive adhesive emulsion comprising mixing the silicone pressure sensitive adhesive defined above with the volatile silicone fluid having a boiling point below 300° C. and adding the resulting mixture to an aqueous solution of a surfactant while shearing." (*See* Column 2, lines 1-6). Furthermore, Kosal provides that, "[t]he volatile silicone fluid of boiling point below 300° C. can be a linear or cyclic polysiloxane, preferably a polydiorganosiloxane in which the organo groups are hydrocarbon groups having 1 to 6 carbon atoms, and most preferably a polydimethylsiloxane." (*See* Column 3, lines 44-48). Kosal further discloses that, "[t]he volatile silicone fluid is preferably used at 30-150 percent by weight, most preferably 50-100 percent, based on the silicone pressure sensitive adhesive . . . [and] [t]he volatile silicone fluid allows the silicone

pressure sensitive adhesive to be processed as a liquid of handleable viscosity so that it can be emulsified." (*See* Column 3, lines 57-63).

Thus, it is clear that Kosal does not disclose an oil-in-water emulsion substantially free of lipophilic solvent recited in independent claim 1. As previously discussed, independent claim 1 comprises an oil-in-water emulsion formed by mechanical inversion of a water-in-oil emulsion, without the use of supplemental solvents to reduce the high viscosity of the silicone component. In contrast, Kosal requires the use of a supplemental, volatile silicone fluid that "allows the pressure sensitive adhesive to be processed as a handleable viscosity so that it can be emulsified." (*See* Column 3, lines 61-63). As a result, Kosal fails to recite an oil-in-water emulsion that is substantially free of lipophilic solvent and formed by mechanical inversion, as recited in independent claim 1.

The Examiner has failed to provide any references that teach or suggest, either singularly or in combination, a controlled-release composition for topical application to a substrate comprising an oil-in-water emulsion that is substantially free of lipophilic solvent and formed by mechanical inversion of a water-in-oil emulsion. As a result, it is believed that the Examiner's rejection of independent claim 1 under 35 U.S.C. §103(a) is overcome. Additionally, as claims 2-7, 9-12 and 14-17 depend from independent claim 1, it is also believed that the Examiner's rejection of these claims is overcome. Moreover, amended claim 18 also depends from independent claim 1. Thus, it is also believed that claim 18 is also patentable over Kosal, in view of Gray et al., and further in view of Ulrich.

In light of the foregoing, it is submitted that the claims, as amended herein, are allowable. Accordingly, reconsideration and allowance of those claims are earnestly solicited.

Respectfully submitted,

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